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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,239	01/16/2002	Melissa M. Batchelor	RM.7CP	8033
29296	7590	01/24/2006	EXAMINER	
JULIA CHURCH DIERKER DIERKER & ASSOCIATES, P.C. 3331 W. BIG BEAVER RD. SUITE 109 TROY, MI 48084-2813			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/052,239	Applicant(s) BATCHELOR ET AL	
	Examiner David M. Naff	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/28/05 & 11/1/05.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-19 and 30-42 is/are pending in the application.
 4a) Of the above claim(s) 37-41 is/are withdrawn from consideration.
 5) ☒ Claim(s) 9, 13, 14, 19 and 34 is/are allowed.
 6) ☒ Claim(s) 6-8, 10-12, 15-18, 30-33, 35, 36 and 42 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 03 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/20/05, 11/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment of 7/28/05 amended claims 6-10, 13, 17-19, 30, 32-34, added new claims 35-42, and canceled claims 20-29.

Claims in the application are 6-19 and 30-42 are in the
5 application.

A response of 11/1/05 to a restriction requirement of 10/19/05 elected Group I claims 6-19, 30-36 and 42 with traverse.

Applicant's election of Group I claims 6-19, 30-36 and 42 with traverse in the reply filed on 11/01/05 is acknowledged. Because
10 applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 37-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being
15 no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/01/05.

Claims examined on the merits are 6-19, 30-36 and 42.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

20 ***Claim Rejections - 35 USC § 112***

Claims 6-8, 10-12, 15-18, 30-33, 35, 36 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably
25 convey to one skilled in the relevant art that the inventor(s), at the

time the application was filed, had possession of the claimed invention.

Adequate support is not found in the specification for "macrocyclic ligand" as claimed in the context of claim 6 and claims dependent thereon, and for "planar square geometry" claimed in the context of claim 30 and claims dependent thereon. While page 3, line 23, uses the term macrocyclic ligands, this is only in connection with specific materials, and does not support that the catalytic agent was to include any macrocyclic ligand.

While the specification recites "planar square-type geometry" (page 3, lines 18-19) the term "planar square geometry" is not recited. The term "planar square-type geometry" is not defined in the specification, and it is unclear as to the type of geometry required by the term. A type of square geometry is not a square geometry. Furthermore, the term is used only in connection with a specific catalytic agent, and there is not support for the catalytic agent being any catalytic agent as claimed having a planar square geometry.

Claim Rejections - 35 USC § 112

Claims 6-8, 10-12, 15-18, 30-33, 35, 36 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear in using the terms "macrocyclic ligand" and "planar square geometry" since the meaning and scope of the terms is uncertain in the claims. The specification

fails to define metes and bounds of the terms to enable one to know when a catalytic agent does and does not contain a "macrocyclic ligand" and "planar square geometry".

Claim Rejections - 35 USC § 102

5 Claims 6-8, 10-12 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Fauquex et al (5,990,289) or Staples et al (5,169,936).

10 The claims are drawn to a material containing an immobilized catalytic agent having nitrite reductase, nitrate reductase or nitrosothiol reductase activity that converts nitrite, nitrate or nitrosothiols to nitric oxide when in contact with blood. The catalytic agent may include a macrocyclic ligand (claim 6) or have a planar square geometry (claim 42), and the agent can be a Cu(II) metal ion ligand complex.

15 Fauquex et al (col 2, lines 10-35) and Staples et al (col 7, lines 15-50) disclose Cu(II) bound to a polymeric material via a chelating group for use in purifying protein.

20 The Cu(II) bound to a polymeric material of Fauquex et al or Staples et al is a material as presently claimed. The Cu(II) is inherently capable of functioning as a nitrite reductase when in contact with blood to produce nitric oxide. The chelating group is a ligand as required by claims that require a ligand, and results in a Cu(II) metal ion ligand complex as in claim 8. The chelating group can be considered to include a macrocyclic ligand when the term is
25 given its broadest interpretation. In regard to claim 42, the Cu(II)

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in combination with a chelating group as disclosed by the references is inherently a planar square-type geometry as disclosed in the specification.

Response to Arguments

5 Applicants urge that the references do not disclose a macrocyclic ligand. However, the chelating group of the references is inherently a macrocyclic ligand. Applicants have not pointed out any structure that is necessitated by a macrocyclic ligand that is not contained by the chelating group of the references.

10 Applicants urge that they disagree with the examiner's assertion that Cu(II) is inherently capable of functioning as a nitrite reductase. However, the present invention can use Cu(II) as a catalytic agent, and applicants have provided no specific reasons why the Cu(II) of the references will not also function as a nitrite
15 reductase.

Claim Rejections - 35 USC § 103

Claims 6-8, 10-12, 15-18, 30-33 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sivan et al (6,569,688) in view of Fauquex et al or Stamples et al each taken with Fanning et al
20 (5,858,792), and if necessary in further view of Tedeschi et al (6,645,518).

Claims 6-8, 10-12 and 42 are described above.

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Claims 15-18 and 30-33 require the material to be a metal or a medical device, and claims 30-33 require the ligand to have a planar square geometry.

5 Sivan et al disclose an intravascular apparatus such as a stent, which can be made of a metal (col 3, lines 60-61), containing an immobilized enzyme such as a nitrogen oxide synthase to produce nitric oxide (col 3, lines 45-66 and col 4, lines 40-39).

Fauquex et al and Stamples et al are described above.

10 Fanning et al disclose using copper to reduce nitrate to nitrite (col 3, lines 15-20) and measuring nitrite from nitric oxide produced from nitrite (col 9, lines 1-10).

Tedeschl et al disclose a medical device such as a stent having a nitric oxide releasing coating (col 8, lines 30-49).

15 It would have been obvious to immobilize Cu(II) in place of the nitrogen oxide synthase of Sivan et al as suggested by Fauquex et al or Stamples et al immobilizing Cu(II) on a polymeric material since it would have been expected from Fanning et al that Cu can reduce nitrite to produce nitric oxide. When substituting the Cu(II), it would have been obvious to use a chelating group for bonding the Cu(II) to a
20 polymer as suggested by Fauquex et al or Stamples et al. The chelating group of Fauquex et al or Stamples et al can be considered a macrocyclic ligand and have a planar square-type geometry as disclosed in the specification. If needed, Tedeschl et al would have further suggested a coating on a medical device that releases nitric oxide.

Response to Arguments

Applicants rely on the type of arguments responded to above, and these arguments are unpersuasive for reasons set forth above.

Additionally, the specification fails to support that planar square-
5 type geometry was to be limited to a metal ion center with four atoms at four corners. A "type" of square as disclosed in the specification is not a square as applicants are now asserting the claims require.

An Exhibit 1 was not attached to the amendment.

Conclusion

10 Claims 9, 13, 14, 19 and 34 are allowed.

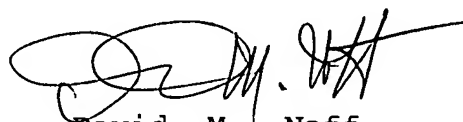
Claims 35 and 36 are free of the prior art.

Any inquiry concerning this communication or earlier
communications from the examiner should be directed to David M. Naff
whose telephone number is 571-272-0920. The examiner can normally be
15 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,
the examiner's supervisor, Mike Wityshyn can be reached on 571-272-
0926. The fax phone number for the organization where this
application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN

1/23/06